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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,815	06/25/2001	Mitsutoshi Tatara	159-64	6708

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Nixon & Vanderhye
8th Floor
1100 North Glebe Road
Arlington, VA 22201-4714

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/786,815	TATARA ET AL.
	Examiner Liliana Di Nola-Baron	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13, 16 and 17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-13, 16 and 17 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. _____.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Receipt of Applicant's amendment, filed on March 17, 2003, is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 6-9 recite the limitation "as the other additive(s)" in the last line of the claims.

There is insufficient antecedent basis for this limitation in the claims, since Applicant's amendment has deleted the phrase "other additive" in independent claim 1. It is suggested to amend claims 6-9 to read on the limitation "as additive". It is also suggested to amend the phrase "other additive" in claim 16 to read on "additive" or "one or more additives".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b)

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only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 12-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Lerner et al. (U.S. Patent 6,197,331).

The claimed invention is directed to a pharmaceutical base comprising a water-insoluble polymer, a solvent and optionally additives, and an agent for treatment of periodontal disease comprising an active ingredient, a water-insoluble polymer, a solvent and optionally additives.

Lerner et al. provides a sustained or controlled release composition for topical application in the oral cavity to teeth or dental structure, said composition comprising a drug, a polymer, preferably Eudragit, adhesives, release-adjusting agents, such as pH adjustors, and a plasticizer (a solvent), including triethyl citrate, dibutylphthalate, diethylphthalate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate, triacetin, polyethylene glycol and castor oil (See col. 9, line 10 to col. 12, line 5). Lerner et al. discloses a method for making said composition, comprising adding the plasticizer and the drug to the polymer, and teaches that the composition may include flavorants, sweeteners and colorants (See 12, line 60 to col. 13, line 61). Lerner et al. include anti-inflammatory agents, anesthetics, antibiotics and antifungal drugs among the active agents used in the invention (See col. 15, line 12 to col. 16, line 63).

The compositions and methods disclosed by Lerner et al. meet the limitations of claims 12-13 and 16 of the instant application, as they contemplate a pharmaceutical base comprising a water-insoluble polymer, a solvent and optionally additives, and a composition comprising an active

ingredient, a water-insoluble polymer, a solvent and optionally additives. Thus, Lerner et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Patent 5,648,399).

Friedman et al. provides methods for the treatment of gingivitis, oral plaque and oral infections by the administration of a liquid composition comprising methacrylic acid copolymer and an active agent and teaches that the composition forms a solid film upon drying and is capable of providing sustained release of the active agent (See Abstract). Friedman et al. includes Eudragit L, Eudragit S, Eudragit RL and Eudragit RS among the polymers used in the invention (See col. 8, lines 6-15), anti-fungal, antibiotic, anti-viral, anti-inflammatory agents and growth factors among the active agents used in the invention (See col. 10, line 64 to col. 11, line 5), and teaches that the composition may comprise plasticizers, such as dibutyl phthalate, an adhesive polymer, a coloring agent (powder) (See col. 11, lines 16-25), citric acid, lysine and aspartic acid, which are pH adjustors, and lipids (oils and fats) (See col. 11, lines 54-61). Friedman et al. includes penicillins among the antibiotics used in the invention (See col. 13, lines 15-20). With respect to

the method of preparing the composition of the invention claimed in claim 17, the patent teaches in Example 1, that the polymer and the drug are dissolved in ethanol (a solvent, which is compatible with water) and additional components are added after complete dissolution of the ingredients.

Thus, the patent provides liquid compositions comprising an active ingredient, a water-insoluble polymer, a solvent and optionally additional additives, and teaches that the compositions form a solid film upon drying and is capable of providing sustained release of the active agent.

Friedman et al. does not specifically teach that the compositions of the invention are in the form of cream or ointment, as claimed in claims 1-11, however, the patent teaches that the liquid compositions are applied to a tooth by brush or spray and dry as a film adhering to the surface of the tooth. It is the view of the examiner that creams and ointments can be applied by brush to the tooth.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Friedman et al., to provide compositions for the treatment of oral infection capable to harden into film upon application in the oral cavity and provide sustained release of the pharmaceutical agent. The expected result would have been a successful antibacterial composition for topical application in the oral cavity and successful methods for making said composition. Because of the teachings of Friedman et al., that liquid compositions comprising an active ingredient, a water-insoluble polymer, a solvent and optionally additional additives form a solid film upon topical application and provide sustained or controlled release of the active agent, one of ordinary skill in the art would have a reasonable

expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 1-13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerner et al. in view of Ganguly et al. (U.S. Patent 4,743,598).

Lerner et al. provides a sustained or controlled release composition for topical application in the oral cavity to teeth or dental structure, said composition comprising a drug, a polymer, preferably Eudragit, adhesives, release-adjusting agents, such as pH adjustors, and a plasticizer, including triethyl citrate, dibutylphthalate, diethylphthalate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate, triacetin, polyethylene glycol and castor oil (See col. 9, line 10 to col. 12, line 5). Lerner et al. discloses a method for making said composition, comprising adding the plasticizer and the drug to the polymer, and teaches that the composition may include flavorants, sweeteners and colorants (See 12, line 60 to col. 13, line 61). Lerner et al. includes anti-inflammatory agents, anesthetics, antibiotics and antifungal drugs among the active agents used in the invention (See col. 15, line 12 to col. 16, line 63). With respect to the limitation "wherein said composition is formulated as a cream or ointment which hardens at least in the surface portion of the cream or ointment when topically applied", Lerner et al. teaches that the invention is directed to a liquid composition that is capable of drying to form a composition that will effectively release the pharmaceutical in the oral cavity (See col. 10, lines 38-44) and the material used in the composition is soft, so that it conforms to the contour of the tooth, or other

hard structure in the oral cavity (See col. 12, lines 43-50). Thus, even though Lerner et al. does not specifically teach that the composition of the invention is in the form of cream or ointment, it teaches that the composition is soft and is capable of drying to form a composition that will effectively release the pharmaceutical in the oral cavity.

Lerner et al. is deficient in the fact, that it does not specifically mention a penem antibiotic claimed in claim 11 among the antibiotics listed in the patent.

Ganguly et al. discloses penem antibiotics and teaches that the compounds of the invention are conventionally formulated in pharmaceutical compositions comprising polymers, oils, fillers, binders, disintegrants and buffering agents, for topical application (See col. 1, line 16 to col. 3, line 61). Specifically, Ganguly et al. teaches that topical formulations are in the form of lotions, creams and ointments (See col. 3, lines 29-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include penem antibiotics in the compositions disclosed by Lerner et al., to increase the effectiveness of the composition against microorganisms. The expected result would have been a successful antibacterial composition for topical application in the oral cavity and successful methods for making said composition. Because of the teachings of Lerner et al., that sustained or controlled release composition for topical application in the oral cavity may comprise antibiotics, and the teachings of Ganguly et al., that penem antibiotics can be formulated in pharmaceutical compositions for topical application, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant

application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

9. Applicant's arguments, filed on March 17, 2003, have been fully considered, but they are not persuasive.
10. Applicant argues that Lerner et al. discloses a patch, which does not harden at a site of application and teaches against using ointments in the oral cavity. In response to said argument, it is noted that Lerner et al. teaches that the invention is directed to a liquid composition that is capable of drying to form a composition that will effectively release the pharmaceutical in the oral cavity (See col. 10, lines 38-44) and the material used in the composition is soft at the time of application, so that it conforms to the contour of the tooth, or other hard structure in the oral cavity (See col. 12, lines 43-50). Thus, even though Lerner et al. does not specifically teach that the composition of the invention is in the form of cream or ointment, it teaches that the composition is soft and is capable of drying to form a composition that will effectively release the pharmaceutical in the oral cavity.
11. In response to Applicant's argument, that Ganguly et al. does not suggest anything about the possibility of keeping a cream or ointment at the site of application, it is noted that Ganguly et al. teaches that topical formulations are in the form of lotions, creams and ointments (See col. 3, lines 29-31). The examiner relies on Lerner et al. for the teachings that liquid compositions are

capable of drying to form compositions that will effectively release the pharmaceutical in the oral cavity.

12. Applicant's amendment has overcome the 35 U.S.C. 102(e) rejection of claims 1-11 over Lerner et al. of the previous Office action. Accordingly, said rejection is withdrawn.

Conclusion

13. Claims 1-13, 16 and 17 are rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LNB3

May 1, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600